

# CARAFATE®

(sucralfate) 1gm Tablets

## BRIEF SUMMARY

## CONTRAINDICATIONS

There are no known contraindications to the use of sucralfate.

## PRECAUTIONS

Duodenal ulcer is a chronic, recurrent disease. While short-term treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the post-healing frequency or severity of duodenal ulceration.

**Drug Interactions:** Animal studies have shown that simultaneous administration of CARAFATE (sucralfate) with tetracycline, phenytoin, digoxin, or omeprazole will result in a statistically significant reduction in the bioavailability of these agents. The bioavailability of these agents may be restored simply by separating the administration of these agents from that of CARAFATE by two hours. This interaction appears to be non-systemic in origin, presumably resulting from these agents being bound by CARAFATE in the gastrointestinal tract. The clinical significance of these animal studies is yet to be defined. However, because of the potential of CARAFATE to alter the absorption of some drugs from the gastrointestinal tract, the separate administration of CARAFATE from that of other agents should be considered when alterations in bioavailability are felt to be critical for concomitantly administered drugs.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Chronic oral toxicity studies of 24 months' duration were conducted in mice and rats at doses up to 1 gm/kg (12 times the human dose). There was no evidence of drug-related tumorigenicity. A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies were not conducted.

**Pregnancy:** Teratogenic effects. Pregnancy Category B. Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

**Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness in children have not been established.

## ADVERSE REACTIONS

Adverse reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,500 patients treated with sucralfate, adverse effects were reported in 121 (4.7%).

Constipation was the most frequent complaint (2.2%). Other adverse effects, reported in no more than one of every 350 patients, were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

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## LETTERS TO THE EDITOR

The Journal welcomes Letters to the Editor. If found suitable, they will be published as space allows. Letters should be typed double-spaced, should not exceed 400 words, and are subject to abridgment and other editorial changes in accordance with Journal style.

### PRENATAL SCREENING FOR HEPATITIS B

To the Editor:

José Arevalo and Manuel Arevalo (*Prevalence of hepatitis B in an indigent, multiethnic community clinic prenatal population. J Fam Pract 1989; 29:615-619*) point out the justification for routine prenatal screening for hepatitis B surface antigen—I strongly concur. I have heard at least one physician state his belief in his own ability to recognize patients at risk. However, the old Centers for Disease Control (CDC) screening criteria are inadequate, as the literature shows,<sup>1,2</sup> even when additional criteria are added.<sup>2</sup> The CDC<sup>3</sup> and the US Preventive Services Task Force<sup>4</sup> recommend that *all* pregnant women be tested for hepatitis B surface antigen. Ninety percent of newborns who become infected with hepatitis B become carriers<sup>5</sup> and, therefore, have 223 times the risk for developing hepatocellular carcinoma than noncarriers.<sup>6</sup> As the combination of the recombinant vaccine and hepatitis B immune globulin fails only in 3.6% of cases,<sup>7</sup> the burden of disease can be greatly reduced. This instance is the first of a vaccine-preventable cancer. The efforts of individual physicians as well as hospital policies for mandatory universal prenatal screening are needed to limit hepatitis B.

Among those populations at greatest risk in the United States are the nearly 1 million Southeast Asian refugees, whose prevalence rate for hepatitis B surface antigen is 13.3%.<sup>8</sup> Universal or mass hepatitis B immunization programs have been successfully tested in China,<sup>9</sup> Taiwan,<sup>10</sup> and Singapore.<sup>11</sup> A recent study shows that 46% of cases of infection in offspring born in the United States to Southeast Asian refugees are not attributable to vertical transmission.<sup>12</sup>

It concludes that horizontal transmission must be occurring, both within and between households.<sup>12</sup> The United States has begun universal hepatitis B vaccination in the refugee camps in Thailand for children up to 7 years of age. New CDC recommendations suggest hepatitis B vaccination for *all infants born to women who were born in areas where hepatitis B is endemic*.<sup>13</sup> Furthermore, *children less than seven years of age from refugee families should be considered for hepatitis B immunization even if no family members are carriers*.<sup>13</sup>

One major barrier to effective immunization is poor compliance. The second and third doses need to be given on time, that is, at 1 and 5 months, respectively, after the first. A particular problem can occur when one physician does the inpatient newborn care and another sees the infant for well-baby examinations. In St Paul, Minnesota, a tracking system by the Health Department has begun to ensure that infants obtain their follow-up doses.

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## OBSTETRIC TRAINING

To the Editor:

I read with interest Drs Peterson, Reiss, and Wadland's article "Restructuring a Family Practice Obstetrics Curriculum" (*J Fam Pract* 1990; 30:81-85). They should be commended for the amount of work they put into developing family practice obstetrics at the University of Vermont.

Our experience in Cedar Rapids, Iowa, would indicate that some of their education and procedure training is being delayed unnecessarily. For instance, vaginal delivery after cesarean (VBAC) can be accomplished by a first-year resident, pro-

vided the resident has faculty backup. Similarly, low-forceps vacuum assist, pH sampling, fourth-degree episiotomy repair, nonstress testing, first assist at cesarean section and tubal ligation, and suction curettage for first-trimester abortion are all procedures that are within the skills of a first-year resident, again provided a faculty member is present and assisting. Delaying introduction of these procedures until the second or third year only shortens the amount of time a resident has to become familiar and competent in the procedures.

Clearly the circumstances under which the curriculum was developed are different in a university setting compared with our community setting, and one can only hope that with time and experience the obstetrics curriculum can be modified.

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## ULTRASOUND SCREENING DURING PREGNANCY

To the Editor:

In the published debate "Should Ultrasound Be Used Routinely During Pregnancy?" (*J Fam Pract* 29: 657-664, 1989), the two authors "consider similar evidence, but end up at opposite poles in its interpretation." We submit that this may have happened because the authors approached the question from different standpoints, the first of which could be termed *empirical*, and the second of which could be described as *scientific*. Brief examination of the two articles illustrates this contrast.

In the first article, "An Affirmative View,"<sup>1</sup> Dr Youngblood outlines many potential benefits of routine ultrasound, but only rarely are these points supported by scientific studies. Rather, he refers most often to review articles and a retrospective study that was performed in his own practice in which there was no concomitant control group. There is no

mention of possible adverse effects of routine ultrasound. When evaluating randomized controlled trials, Dr Youngblood provides details of the only study (out of four) showing a beneficial outcome, which was reported in letter format. Dr Youngblood concludes by stating: "I continue to affirm my conviction that timely and routine scanning in early pregnancy is beneficial."

In the second article, "An Opposing View,"<sup>2</sup> Dr Ewigman begins by appropriately identifying routine ultrasound as a screening test. He then examines the procedure within the context of established concepts of screening,<sup>3</sup> frequently citing primary scientific studies as evidence. In a balanced manner, he discusses issues of sensitivity, specificity, predictive value, patient acceptance, and safety. Unlike Dr Youngblood, Dr Ewigman reviews all of the clinical trials, providing cogent analysis of methods and results along with an overall summary of findings. His conclusion is that "evidence does not support the use of ultrasonography as a screening procedure."

These two approaches—empirical vs scientific—are commonly used by physicians when deciding practice policies. Regarding ultrasound, trials in England and America are currently underway that will provide more definitive answers.<sup>4</sup> In the meantime, however, clinical practice moves ahead, obviating the need for physicians to evaluate current data critically. While acknowledging the great value of experiential learning in medicine, we strongly urge clinicians to combine this with scientific principles whenever possible.

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## PROCEDURES IN FAMILY PRACTICE

To the Editor:

After reading Dr Rodney's eloquent response<sup>1</sup> to the controversy on office procedures, I could not help but reply in support of his position. We cannot allow our specialty to remain "in diagnostic darkness," as he stated, and, I would add, therapeutic darkness. Our specialty is supposed to pride itself in prevention and wellness and health maintenance, and above all, to be cost effective while providing comprehensive care with continuity, not "fragmentation of health care." Certainly this includes procedural activity in its current definition. Are we losing sight of basic concepts on which our specialty was founded?

Family medicine is still one of the most frequent sites of entry into the medical care system. With that fact and our belief in the above principles,

the use of diagnostic procedures and treatment techniques that in the office are safe and simple should be part of our capability. Additionally and of great importance, I feel, is that they facilitate a more precise referral process. We are not simply triage physicians.

I find the previous commentary by Drs Ruane and Hudson,<sup>2</sup> who interpreted the evidence on endometrial biopsies to mean "most family physicians have found that including this procedure in their practices does not add materially to the quality of care their patients receive," to be wanting. As Dr Rodney pointed out, use of the Unimar pipelle has greatly simplified the procedure, and when we look at the current at-risk indications for this procedure, it is a service we certainly should provide our patients that realistically adds very little time to an office visit.

I believe many of our colleagues feel that the use of up-to-date, simple, safe techniques and equipment for diagnosis and treatment of numerous problems encountered with high frequency demands our involvement. Additional training may be necessary. Certainly current teaching activities in the area of procedural skills that include endometrial biopsies, sponsored by our own American Academy of Family Physicians and based on well-documented member-

ship needs survey, support this involvement.

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2. Rosenthal TC, Perrapato TH, Doemland MS, et al: Endometrial sampling: Analysis of 310 procedures performed by family physicians. Ruane TJ, Hudson JW: Commentary. *J Fam Pract* 1989; 29:249-256

## CORRECTION

Following the Commentary by Steven Zweig to the article by Glik et al in the February issue (*Antihypertensive regimen and quality of life in a disadvantaged population, J Fam Pract* 1990; 30:143-152), Dr Zweig's affiliation should have been stated: Dr Zweig is Assistant Professor in the Department of Family and Community Medicine, University of Missouri-Columbia School of Medicine. The Publisher regrets this omission.